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STATUTORY INSTRUMENTS

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**1992 No. 3146**

**CONSUMER PROTECTION**

**The Active Implantable Medical Devices Regulations 1992**

*Made* - - - - *10th December 1992*  
*Laid before Parliament* *11th December 1992*  
*Coming into force* - - *1st January 1993*

The Secretary of State, in exercise of the powers conferred by sections 11 and 27(2)(b) of the Consumer Protection Act 1987(1), after consultation in accordance with section 11(5) of that Act with organisations appearing to her to be representative of interests substantially affected by these Regulations, with such other persons as appear to her to be appropriate and with the Health and Safety Commission, and the Secretary of State as respects Great Britain and the Department of Health and Social Services for Northern Ireland as respects Northern Ireland, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(2) and in each case in exercise of all other powers so enabling them, hereby make the following Regulations:—

**Citation and commencement**

1. These Regulations may be cited as the Active Implantable Medical Devices Regulations 1992 and shall come into force on 1st January 1993.

**Interpretation**

2.—(1) In these Regulations, unless the context requires otherwise—

“the 1987 Act” means the Consumer Protection Act 1987;

“authorised representative” means an authorised representative established within the European Economic Community;

“custom—made” means, in relation to a device,

- (a) that it is manufactured specifically in accordance with a medical specialist’s written prescription which gives, under his responsibility, specific characteristics as to its design, and
- (b) that it is intended to be used only for a particular patient;

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(1) 1987 c. 43.

(2) See S.I.1991/2289, Article 2, which designates the Secretary of State and the Department of Health and Social Services for Northern Ireland for the purposes of section 2(2) in relation to active implantable medical devices.

“device” means an active implantable medical device, that is to say an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software necessary for its proper functioning, which—

- (a) is intended by the manufacturer to be used for human beings—
  - (i) in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
  - (ii) in the investigation, replacement or modification of the anatomy or of a physiological process, or
  - (iii) in the control of conception;
- (b) does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, even if it is assisted in its function by such means;
- (c) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and
- (d) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced;

even if it is intended to administer a medicinal product as defined in the Medicines Act 1968<sup>(3)</sup> or incorporates as an integral part a substance which, if used separately, would be a medicinal product as so defined;

“the Directive” means Council Directive [90/385/EEC](#) on the approximation of the laws of member States relating to active implantable medical devices<sup>(4)</sup>;

“EC mark” means the mark which indicates that one or more of the procedures referred to in regulation 5 has been followed and which consists of a symbol comprising the letters “CE” of which an illustration is given in Schedule 1;

“essential requirements” means the requirements specified in Schedule 2 and “relevant essential requirements” in relation to a device means such of those requirements, or such aspects of those requirements, as apply to it, not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation;

“harmonised Standard” means a technical specification adopted by the European Committee for Standardisation or the European Committee for Electrotechnical Standardisation, or both of them, upon a remit from the Commission of the European Economic Community pursuant to Council Directive [83/189/EEC](#)<sup>(5)</sup> laying down a procedure for the provision of information in the field of technical standards and regulations, as amended by Council Directive [88/182/EEC](#)<sup>(6)</sup> and Council Directive [90/320/EEC](#)<sup>(7)</sup>, and the reference of which has been published in the Official Journal of the European Communities;

“intended for clinical investigation” means, in relation to a device, that it is intended for use by a medical specialist when conducting clinical investigations of that device;

“intended purpose” means, in relation to a device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;

“medical specialist” means a registered medical practitioner who has a qualification as, or is undergoing training intended to lead to qualification as, a specialist;

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(3) 1968 c. 67; see section 130.

(4) OJ No. L189, 20.7.90, p. 17.

(5) OJ No. L109, 26.4.83, p. 8.

(6) OJ No. L81, 26.3.88, p. 75.

(7) OJ No. L128, 18.5.90, p. 15.

“member State” means a member State of the European Economic Community;

“notified body” means, in relation to any task, a body designated and notified in respect of that task in accordance with Article 11 of the Directive;

“placed on the market” means, in relation to a device, first supplied or first made available for supply in the United Kingdom otherwise than for the purpose of its export—

- (a) to another country which is not a member State, and
- (b) for use in a country that is not a member State;

“put into service” means make available to registered medical practitioners for implantation;

“relevant national Standard” means, in relation to an essential requirement or an aspect of it, a Standard—

- (a) which contains a technical specification or a description relating to that requirement or aspect,
- (b) which corresponds to a harmonised Standard containing such a specification or description, and
- (c) of which the reference number is published in the United Kingdom by the Secretary of State by notice in the London, Edinburgh and Belfast Gazettes or in another member State of the European Economic Community;

“relevant notified body logo” means the logo of the notified body which was responsible for carrying out tasks of the notified body under paragraph 5 of Annex 2 to, under Annex 4 to, or under paragraph 4 of Annex 5 to, the Directive as respects a procedure which has been followed by the manufacturer of a device, and, where there is more than one such notified body, means the logo of each of them.

(2) In these Regulations, unless the context requires otherwise, a reference to a numbered regulation is a reference to the regulation of these Regulations which is so numbered; a reference in a regulation of, or Schedule to, these Regulations to a numbered paragraph is a reference to the paragraph of that regulation or Schedule which is so numbered, and a reference in a paragraph to a numbered sub—paragraph is a reference to the sub—paragraph of that paragraph which is so numbered.

### **Essential requirements for devices**

**3.—(1)** All devices placed on the market or put into service must comply with the relevant essential requirements.

(2) In determining which are the relevant essential requirements for a device and whether or not the device complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(3) Any determination that a device complies with any of the essential requirements specified in paragraphs 1 to 5 of Schedule 2, and any evaluation of side effects or undesirable effects for the purposes of determining whether or not a device complies with any of the essential requirements, shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Schedule 3; and any determination as to whether or not a device complies with any other essential requirements may be based on such data.

(4) In the case of a device which has been put into service, the essential requirements specified in paragraphs 13, 14 and 15 of Schedule 2 are complied with only if the information and particulars referred to in those paragraphs are in English (whether or not they are also in another language).

(5) A device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national Standard, unless there are reasonable grounds for suspecting that the device does not comply with that requirement.

(6) A device which is neither custom—made nor intended for clinical investigation and which bears the EC mark shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(7) A custom—made device in respect of which the conditions specified in Schedule 4 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Schedule 4 shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(8) A device intended for clinical investigation in respect of which —

- (a) notice has been given under regulation 7(1);
- (b) no notice has been given under regulation 7(2) within the period of 60 days there referred to; and
- (c) the conditions specified in Schedule 4 are satisfied,

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

### **EC mark**

4.—(1) Except as provided by paragraph (2), every device placed on the market or put into service shall bear the EC mark (affixed following a procedure mentioned in regulation 5, whether carried out in the United Kingdom or elsewhere) in a visible, legible and indelible form —

- (a) on the sterile pack;
- (b) on any sales packaging; and
- (c) on the instruction leaflet,

and the mark shall in each case be accompanied by the relevant notified body logo for that device.

(2) Paragraph (1) does not apply to a device which is custom—made or intended for clinical investigation, and such devices shall not bear the EC mark.

(3) No device placed on the market or put into service shall bear (whether on its pack, sales packaging or instruction leaflet or elsewhere) a mark which is likely to be confused with the EC mark.

### **Procedure for affixing EC mark**

5.—(1) A device may bear the EC mark only if its manufacturer —

- (a) follows the EC declaration of conformity procedure; or
- (b) follows the EC type—examination procedure, together with —
  - (i) the EC verification procedure, or
  - (ii) the EC declaration of conformity to type procedure.

(2) The EC declaration of conformity procedure is the procedure by which the manufacturer —

- (a) applies an approved quality system for the design, manufacture and final inspection of devices, and is subject to surveillance to ensure that he duly fulfils his obligations arising from the approved quality system;
- (b) ensures and declares that the devices satisfy the relevant provisions of the Directive and, in particular, the relevant essential requirements; and

- (c) having applied the EC mark in accordance with regulation 4, draws up and keeps a written declaration of conformity with the relevant provisions of the Directive, covering one or more identified specimens of the devices,

and Schedule 5 (Part I of which relates to the quality system, including the design dossier, and Part II of which relates to surveillance) shall have effect for the purposes of that procedure.

(3) The EC type—examination procedure is the procedure by which a notified body ascertains and certifies that a representative sample of the production of devices envisaged satisfies the relevant provisions of the Directive; and Schedule 6 shall have effect for the purposes of that procedure.

(4) The EC verification procedure is the procedure by which a notified body verifies and certifies that devices conform to the type described in an EC type—examination certificate and satisfy the relevant provisions of the Directive; and Schedule 7 shall have effect for the purposes of that procedure.

(5) The EC declaration of conformity to type procedure is the procedure by which the manufacturer —

- (a) applies a quality system approved for the manufacture of devices and conducts a final inspection of the devices;
- (b) is subject to surveillance;
- (c) ensures and declares that the devices conform to the type described in an EC type—examination certificate and conform to the relevant provisions of the Directive; and
- (d) having applied the EC mark in accordance with regulation 4, draws up and keeps a written declaration of conformity with the relevant provisions of the Directive covering one or more identified specimens of the devices,

and Schedule 8 (Part I of which relates to the quality system and inspection and Part II of which relates to surveillance) shall have effect for the purposes of that procedure.

(6) Any part of the EC type—examination procedure or the EC verification procedure which is to be followed in the United Kingdom by a manufacturer who has no place of business there may instead be followed by his authorised representative.

(7) The documentation relating to any of the procedures mentioned in this regulation carried out in the United Kingdom shall be in English or, subject to regulation 3(4), in some other language acceptable to the notified body concerned.

(8) A notified body may charge a fee in accordance with paragraphs (9), (10) and (11) for anything done in, or in connection with, performing a function under this regulation or under any of the Schedules referred to in it.

(9) Except as provided by paragraph (10) the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(10) Where the notified body is a body the activities of which are carried on for profit, the fee for doing anything may include an amount representing a profit which is reasonable in the circumstances, having regard to —

- (a) the character and extent of the work done or to be done by the notified body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(11) The notified body may require payment of a fee or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.

### **Custom—made devices**

6.—(1) The manufacturer of a custom—made device shall —

- (a) satisfy the conditions specified in Schedule 4 (as it applies to custom—made devices) before that device is placed on the market or put into service; and
- (b) take all necessary measures to ensure that the manufacturing process ensures that the device manufactured to that process conforms to the documentation referred to in paragraph 3(a) of Schedule 4.

(2) The conditions specified in paragraph 1 of Schedule 4 may be satisfied by the manufacturer's authorised representative, instead of by the manufacturer.

### **Clinical investigations**

7.—(1) Before devices intended for clinical investigation are made available to a medical specialist for the purposes of a clinical investigation to take place within the United Kingdom their manufacturer or his authorised representative shall give at least 60 days' prior notice in writing to the Secretary of State of the making available of the devices for the intended investigation, in the form of the statement provided for by paragraphs 1 and 2(2) of Schedule 4 and the undertaking by the manufacturer mentioned in paragraph 3 of that Schedule.

(2) If, within 60 days of the giving of that notice, the Secretary of State gives written notice to the manufacturer or his authorised representative, whichever gave the notice to him under paragraph (1), that, on grounds relating to the health or safety of patients, users or others, devices should not be made available for the purposes of those investigations, devices may not be made available for those purposes pursuant to that notice under paragraph (1).

(3) The manufacturer of a device intended for clinical investigation shall take all necessary measures to ensure that the manufacturing process ensures that a device manufactured according to that process conforms to the documentation referred to in paragraph 3(b) of Schedule 4 and may authorise the evaluation, by audit where necessary, of the effectiveness of the measures which he takes pursuant to Schedule 4.

(4) A manufacturer who has given the undertaking mentioned in paragraph (1) shall, if so required by the Secretary of State for the purposes of his functions under paragraph (2), make available to him the documentation which he has undertaken to keep available.

(5) The grounds on which a notice may be given under paragraph (2) include the grounds that the Secretary of State is not satisfied as to the safety of a device for the intended purposes because—

- (a) the manufacturer does not authorise an evaluation by the Secretary of State, whether by means of an audit, an inspection or otherwise, of the effectiveness of the measures referred to in paragraph (3); or
- (b) the manufacturer does not make available to the Secretary of State documentation which he has undertaken to keep available.

### **Notified bodies**

8.—(1) The Secretary of State may approve for the purposes of Article 11 of the Directive any corporate or other body as a body which is to carry out tasks as part of a procedure mentioned in regulation 5 and, if he so approves a body, he shall designate the tasks which it is to carry out.

(2) A body shall be approved under paragraph (1) only if—

- (a) it has applied to be, or agrees to be, so approved;
- (b) it is a body in respect of which the conditions specified in Schedule 9 are fulfilled as respects the tasks which it is to carry out.

(3) The Secretary of State shall withdraw any approval of a body under paragraph (1) if the body so requests or if he considers that it is no longer a body in respect of which the conditions specified in Schedule 9 are fulfilled as respects the tasks which it is to carry out.

(4) The Secretary of State may vary the designation of tasks which a notified body is to carry out by—

- (a) limiting or removing the tasks; or
- (b) on the application of the notified body, extending or adding to the tasks.

(5) Before withdrawing an approval under paragraph (3), otherwise than at the notified body's request, and before effecting a variation under paragraph (4)(a), the Secretary of State shall give to the notified body an opportunity to make representations to him in writing and shall take into account any such representations as are made.

### **Prohibition on supply etc.**

**9.**—(1) Subject to paragraph (6), the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device which has been placed on the market or put into service and which does not comply with the relevant essential requirements is prohibited.

(2) Subject to paragraphs (3) and (6) the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device—

- (a) which does not bear the EC mark as required by regulation 4(1); or
- (b) which bears a mark in contravention of regulation 4(3),

is prohibited.

(3) Paragraph (2)(a) does not apply to a device which is custom—made or intended for clinical investigation.

(4) The supply of a custom—made device in respect of which the manufacturer or his authorised representative has contravened regulation 6 is prohibited.

(5) The supply, in contravention of regulation 7(1) or a notice under regulation 7(2), of a device intended for clinical investigation is prohibited.

(6) Nothing in paragraph (1) or (2) prevents the offer to supply, the exposure for supply or the possession for supply at a trade fair, exhibition, demonstration or similar event of a device which does not comply with the relevant essential requirements or which does not bear the EC mark provided that a notice is prominently displayed at the event, so as to be readily visible to a prospective purchaser, indicating that the device—

- (a) does not comply with those requirements or does not bear that mark; and
- (b) may not be put into service until it complies with the requirements of the Directive.

### **Enforcement etc.**

**10.**—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings or notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act.

(2) Each weights and measures authority and each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to devices.

(3) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non—conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to such goods), and in relation to non—conforming devices Schedule 2 to the 1987 Act

shall have effect as if references to goods being unsafe or safe were references to devices being or not being non—conforming devices.

(4) In paragraph (3) “non—conforming devices” means devices which, whether or not the Secretary of State considers them unsafe, he considers to be devices to which the EC mark has been wrongly applied and to be devices—

- (a) which do not conform as respects a relevant essential requirement to a relevant national Standard where the device is held out as respects that essential requirement as conforming to that Standard; or
- (b) where the devices are ones to which the EC mark has been applied following the EC declaration of conformity procedure, in respect of which the manufacturer or his authorised representative has failed to comply with his obligations under that procedure; or
- (c) where the devices are ones to which the EC mark has been applied following the EC type—examination procedure, which do not conform to the type described in the relevant EC type—examination certificate or which conform to such a type which does not meet the relevant essential requirements.

#### **Transitional provision**

**11.** Nothing in regulation 9(1), (2) or (4) shall prohibit the supply before 1st January 1995 of a device, if the supply of the device is in accordance with the laws of that part of the United Kingdom in which it is supplied as in force on 31st December 1992.

#### **Notification of decisions etc.**

**12.—**(1) Where a decision is taken by the Secretary of State or a notified body under these Regulations which results in the refusal of, or restrictions on, the placing on the market by, or the putting into service by, a person of a device, the Secretary of State who, or the notified body which, took the decision shall forthwith give to that person notice of the decision which shall include—

- (a) a statement of the grounds on which it is based; and
- (b) a statement of any legal remedies available to that person and of any time limits which apply to their exercise.

(2) The provisions of paragraph (1) are in addition to any more specific obligation placed upon the Secretary of State or the notified body elsewhere in these Regulations.

10th December 1992

*Virginia Bottomley*  
One of Her Majesty’s Principal Secretaries of  
State



Sealed with the official seal of the Department of Health and Social Services for Northern Ireland  
this 10th day of December 1992.

L.S.

*F. A. Elliott*  
Permanent Secretary

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SCHEDULE 1

Regulation 2(1)

E C MARK



SCHEDULE 2

Regulation 3(1)

ESSENTIAL REQUIREMENTS FOR ACTIVE IMPLANTABLE MEDICAL DEVICES (CORRESPONDING TO ANNEX 1 OF THE DIRECTIVE)

**General requirements**

1.—(1) The device shall be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down by the manufacturer, its use does not compromise the clinical condition or the safety of the patient.

(2) The device shall not present any foreseeable risk to the person implanting it or to other persons.

2. The device must achieve the performances intended by its manufacturer and, in particular, must be designed and manufactured in such a way that it is suitable for one or more of the following functions as specified by him:—

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- (b) investigation, replacement or modification of the anatomy or of a physiological process;
- (c) control of conception.

3. The characteristics and performances referred to in paragraphs 1 and 2 shall not be adversely affected to such a degree that the clinical condition or safety of the patient or of other persons is compromised during the lifetime of the device expected by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The device shall be designed, manufactured and packed in such a way that its characteristics and performances are not adversely affected if the conditions as to storage and transport laid down by the manufacturer, such as conditions relating to temperature or humidity, are met.

5. Any side effects of the device or undesirable conditions resulting from its use shall be reasonably acceptable risks when weighed against the device's intended performances.

**Requirements as to design and construction**

6. In designing and constructing the device the manufacturer shall comply with principles of safety, taking account of the generally acknowledged state of the art at the time of manufacture.

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7. The device shall be designed, manufactured and packed in a non—reusable packaging according to procedures which are sufficient to ensure that—

- (a) the device is sterile when placed on the market; and
- (b) if handled in accordance with conditions as to storage and transport laid down by the manufacturer, the device remains sterile until the packaging is removed and the device is implanted.

8. The device shall be designed and manufactured in such a way as to remove or minimise so far as is possible—

- (a) the risk of physical injury arising out of its physical features (including its dimensions);
- (b) risks connected with the use of sources of energy, including, in the case of a device which uses electricity, risks arising from lack of adequate insulation, from leakage currents and from overheating;
- (c) risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure, variations in pressure and acceleration;
- (d) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high—frequency surgical equipment;
- (e) risks connected with ionising radiation from any radioactive substance included in the device in compliance with the protection requirements laid down in Directive 80/836/Eurotom(8) as amended by Directives 84/467/Euratom(9) and 84/466/Euratom(10);
- (f) risks which may arise where maintenance and calibration are impossible, including—
  - (i) excessive increase of leakage currents,
  - (ii) ageing of the materials used,
  - (iii) excess heat generated by the device, and
  - (iv) decreased accuracy of any measuring or control mechanism.

9. The device shall be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in paragraphs 1 to 5 with particular attention being paid to—

- (a) the choice of materials used, particularly as regards toxicity;
- (b) mutual compatibility between the materials used and biological tissues, cells and body fluids (account being taken in accordance with regulation 3(2) of the intended use of the device);
- (c) compatibility of the device with any substances which it is intended to administer;
- (d) the quality of the connections, particularly where considerations of safety are involved;
- (e) the reliability of the source of energy;
- (f) if appropriate, the need to make it leakproof;
- (g) proper functioning of the programming and control systems, including software.

10. Where a device incorporates, as an integral part, a substance which, when used separately, is likely to be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC(11), and whose action in combination with the device may result in its bioavailability, the safety, quality and usefulness of the substance, account being taken of the purpose of the device, must be verified

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(8) OJ No. L246, 17.9.80, p. 1.

(9) OJ No. L265, 5.10.84, p. 4.

(10) OJ No. L265, 5.10.84, p. 1.

(11) OJ No. 22, 9.2.65, p. 369.

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by analogy with the appropriate methods specified in Directive [75/318/EEC](#)(12), as last amended by Directive [91/507/EEC](#)(13).

**11.** The device and, if appropriate, its component parts must be identifiable to allow any potential risk in connection with the device or any of its component parts.

**12.** The device shall bear a code by which it and its manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture) and which can be read, if necessary, without the need for a surgical operation.

**13.** When a device or its accessories bear instructions required for the operation of the device or indicate parameters for operating or adjusting it by means of a visual system, such instructions or indications must be understandable to the user and, as appropriate, the patient.

**14.—(1)** The sterile pack of the device must bear, legibly and indelibly, the following particulars where appropriate in the form of generally recognised symbols—

- (a) the method of sterilisation;
- (b) an indication that enables the sterile pack to be recognised as such;
- (c) the name and address of the manufacturer;
- (d) a description of the device;
- (e) if the device is intended for clinical investigation, the words: “exclusively for clinical investigations”;
- (f) if the device is custom—made, the words “custom—made device”;
- (g) a declaration that the device is in a sterile condition;
- (h) the month and year of manufacture;
- (i) an indication of the time limit for implanting the device safely.

**(2)** The sales packaging of the device must bear, legibly and indelibly, the following particulars where appropriate in the form of generally recognised symbols—

- (a) the name and address of the manufacturer;
- (b) a description of the device;
- (c) the purpose of the device;
- (d) the relevant characteristics for its use;
- (e) if the device is intended for clinical investigation, the words: “exclusively for clinical investigation”;
- (f) if the device is custom—made, the words “custom—made device”;
- (g) a declaration that the device is in a sterile condition;
- (h) the month and year of manufacture;
- (i) an indication of the time limit for implanting the device safely;
- (j) the conditions for transporting and storing the device.

**15.—(1)** When placed on the market, each device must be accompanied by instructions for use giving the following particulars—

- (a) the year of authorisation to affix the EC mark;
- (b) the particulars specified in paragraph 14(1)(a) to (g) and (2)(c), (d) and (j);

(12) OJ No. L147, 9.6.75, p. 1.

(13) OJ No. L270, 26.9.91, p. 32

- (c) the performances referred to in paragraph 2 and any undesirable side effects;
  - (d) information allowing the registered medical practitioner to select a suitable device and the corresponding software and accessories;
  - (e) information constituting the instructions for use allowing the registered medical practitioner and, where appropriate, the patient to use the device, its accessories and software correctly;
  - (f) information on the nature of, and scope and times for, operating controls and trials;
  - (g) where appropriate, information on maintenance measures;
  - (h) information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided;
  - (i) information regarding the risk of adverse effects on the device caused by instruments present at the time of specific investigations or treatment, and of adverse effects on instruments present at the time of those investigations or treatment caused by the device;
  - (j) the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilisation; and
  - (k) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.
- (2) The instructions shall also include details allowing the registered medical practitioner to brief the patient on the contra—indications and the precautions to be taken, including, in particular—
- (a) information allowing the lifetime of the energy source to be established;
  - (b) precautions to be taken should changes occur in the device’s performances;
  - (c) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, and similar influences; and
  - (d) information identifying any medicinal products which the device in question is designed to administer.

### SCHEDULE 3

Regulation 3(3)

#### EVALUATION ETC. OF CLINICAL DATA (CORRESPONDING TO ANNEX 7 OF THE DIRECTIVE)

##### **Basis of clinical data**

1.—(1) Adequacy of the clinical data presented as part of the particulars referred to in paragraph 6(2) of Schedule 5 or included in the documentation mentioned in paragraphs 1(c) and 2 of Schedule 6 shall be based, account being taken as appropriate of relevant harmonised Standards, on either:

- (a) a collation of currently available, relevant scientific literature covering the intended use of the device and the techniques for it as well as, if appropriate, a written report making a critical assessment of that collation; or
  - (b) the results of all clinical investigations made, and, in particular, the results of those carried out in accordance with paragraphs 2, 3 and 4.
- (2) All the data presented must remain confidential unless it is essential that they be divulged.

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### **Purpose of clinical investigation**

2. The purposes of the clinical investigation are:
  - (a) to verify that, under normal conditions of use, the performances of the device comply with those indicated in paragraph 2 of Schedule 2; and
  - (b) to determine any undesirable side effects, under normal conditions of use, and assess whether they are reasonably acceptable risks having regard to the intended performance of the device.

### **Ethical considerations in clinical investigation**

3.—(1) Clinical investigations shall be made in accordance with the Declaration of Helsinki approved by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and amended by the 29th World Medical Assembly in Tokyo, Japan, in 1975 and the 35th World Medical Assembly in Venice, Italy, in 1983.

(2) All measures relating to the protection of human subjects must be carried out in the spirit of the Declaration of Helsinki, as so approved and amended.

(3) Sub-paragraphs (1) and (2) apply to every step in the clinical investigation from first consideration of need and justification of the study to publication of results.

### **Methods of clinical investigation**

- 4.—(1) Clinical investigations shall—
  - (a) be performed according to an appropriate plan of investigation which represents the current state of the art and is defined in such a way as to confirm or refute the manufacturer's claims for the device; and
  - (b) include an adequate number of observations to guarantee the scientific validity of the conclusions.

(2) The procedures used to perform the investigations shall be appropriate to the device under examination.

(3) Clinical investigations shall be performed in circumstances equivalent to those which would be found in normal conditions of use of the device.

(4) All appropriate features, including those involving the safety and performances of the device, and its effects on patients, shall be examined.

(5) All adverse events shall be fully recorded.

(6) The investigations shall be performed under the responsibility of an appropriately qualified medical specialist, in an appropriate environment.

(7) The medical specialist shall have access to the technical data regarding the device.

(8) The written report, signed by the responsible medical specialist, shall comprise a critical evaluation of all the data collected during the clinical investigation.

SCHEDULE 4

Regulations 3(7) and (8), 6(2) and 7(1)

CONDITIONS RELATING TO DEVICES FOR SPECIAL PURPOSES  
(CORRESPONDING TO ANNEX 6 OF THE DIRECTIVE)

**Statement**

1.—(1) The manufacturer or his authorised representative shall draw up for custom-made devices or for devices intended for clinical investigation a written statement in English comprising the particulars specified in sub-paragraph (1) or (2) respectively of paragraph 2.

(2) The statement shall be signed by or on behalf of the manufacturer or by his authorised representative.

2.—(1) The particulars referred to in paragraph 1(1) for a custom-made device are—

- (a) particulars allowing the device to be identified;
- (b) a statement affirming that the device is intended for exclusive use by a particular patient, together with his name;
- (c) the name of the registered medical practitioner who wrote the prescription and, if applicable, the name of the clinic concerned;
- (d) the particular features of the device as described in the prescription;
- (e) a statement affirming that the device complies with the essential requirements and, where applicable, indicating which relevant essential requirements have not been wholly complied with, together with the grounds for them not having been wholly complied with.

(2) The particulars referred to in paragraph 1(1) for a device intended for clinical investigation are—

- (a) particulars allowing the device to be identified;
- (b) a plan of the investigation, stating in particular the purpose, scope and number of the devices concerned, the terms of any opinion on the investigation given by a committee or other body which has considered the ethics of the investigation and a description of the precautions taken to protect the health and safety of the patient;
- (c) the name of each registered medical practitioner and of each institution responsible for the investigation;
- (d) each place, date of commencement and duration scheduled for the investigation;
- (e) a statement affirming that the device complies with the relevant essential requirements apart from the aspects constituting the object of the investigations and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient.

**Undertaking**

3. The manufacturer shall undertake to keep available for the Secretary of State—

- (a) for custom-made devices, documentation in English enabling the design, manufacture and performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of the Directive to be assessed;
- (b) for devices intended for clinical investigation, that documentation and the following additional documentation in English:—
  - (i) a general description of the product,

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- (ii) design drawings, particulars of methods of manufacture, in particular as regards sterilisation, and diagrams of parts, sub-assemblies, circuits and similar items,
- (iii) the descriptions and explanations necessary for the understanding of those drawings and diagrams and of the operation of the product,
- (iv) a list of the relevant national Standards applied in full or in part, and a description of the measures taken to comply with the relevant essential requirements where those Standards have not been applied,
- (v) the results of the design calculations, checks and technical tests carried out.

## SCHEDULE 5

Regulation 5(2)

### EC DECLARATION OF CONFORMITY PROCEDURE (CORRESPONDING TO ANNEX 2 OF THE DIRECTIVE)

## PART I QUALITY SYSTEM

### **Application for evaluation of quality system**

1. A manufacturer who wishes to have his quality system for design, manufacture and final inspection approved shall make an application in writing to a notified body for evaluation of his quality system.

2.—(1) The application shall include—

- (a) a description of the type of devices manufacture of which is envisaged;
- (b) details of any relevant national Standard or harmonised Standard with which the devices comply;
- (c) the quality system documentation;
- (d) an undertaking by the manufacturer to fulfil the obligations arising from the quality system as approved;
- (e) an undertaking by the manufacturer to maintain the approved quality system in such a way that it remains adequate and efficacious;
- (f) an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system.

(2) The undertaking referred to in sub-paragraph (1)(f) shall include an obligation for the manufacturer to notify the Secretary of State of the following incidents immediately on learning of them—

- (a) any deterioration in the characteristics or performances of, and any inaccuracies in the instruction leaflet for, a device which might lead to or have led to the death of a patient or a deterioration in the state of his health;
- (b) any technical or medical reason for withdrawal of a device from the market which results in such withdrawal by the manufacturer.



### **Approval and evaluation of quality system**

3.—(1) Approval of a quality system shall not be given unless the conditions specified in subparagraphs (2) to (4) are fulfilled.

(2) The application of the quality system must ensure that the devices conform to the provisions of the Directive which apply to them at every stage, from design to final controls.

(3) All the elements, requirements and provisions adopted by the manufacturer for his quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures, and the documentation must make possible a uniform interpretation of the policies and procedures as to quality such as those programmes, plans, manuals and records which relate to quality.

(4) The documentation referred to in sub-paragraph (3) shall include in particular an adequate description of—

- (a) the manufacturer's objectives as to quality;
- (b) the organisation of the business and in particular—
  - (i) the organisational structure of the organisation and the responsibilities and degrees of authority of the managerial staff, where quality of design and manufacture of devices is concerned;
  - (ii) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design and of the devices, including control of devices which do not conform to harmonised Standards;
- (c) the procedures for monitoring and verifying the design of the products and in particular—
  - (i) the design specifications, including the standards which will be applied and a description of the solutions adopted to fulfil the relevant essential requirements when the relevant national Standards are not applied in full;
  - (ii) the techniques of control and verification of the design, and the processes and systematic actions which will be used when the devices are being designed;
- (d) the techniques of control and of quality assurance at the manufacturing stage and in particular:
  - (i) the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
  - (ii) product-identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
- (e) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the equipment used for testing.

4.—(1) The notified body shall effect an evaluation of the quality system to determine whether it fulfils the conditions specified in paragraph 3(2) to (4), and in doing so shall presume fulfilment of those conditions for a quality system which is in accordance with relevant harmonized Standards.

(2) The team of individuals entrusted with the evaluation shall include at least one person who has already had experience of evaluations of the technology concerned.

(3) The evaluation shall include an inspection at the manufacturer's premises.

(4) A decision as to whether or not approval is given shall be notified to the manufacturer after the final inspection and shall contain a reasoned evaluation and the conclusions of the notified body.

5.—(1) The manufacturer shall inform the relevant notified body of any plan to modify his approved quality system.

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(2) The relevant notified body shall evaluate the proposed modifications and shall determine whether the quality system as proposed to be modified would fulfil the conditions specified in paragraph 3(2) to (4).

(3) A decision as to whether or not to approve the system as modified shall be notified to the manufacturer and shall contain a reasoned evaluation and the conclusions of the relevant notified body.

(4) In this paragraph “relevant notified body” in relation to a quality system means the notified body which approved it, except that where that body is no longer a notified body as respects tasks under this paragraph, it means such other notified body as the Secretary of State shall have designated as the notified body in relation to those tasks and that system.

### **Design dossier**

6.—(1) A manufacturer who makes an application under paragraph 1 relating to a type of device shall also make an application for examination of the design dossier relating to that type of device which he plans to manufacture.

(2) The application shall describe the design, manufacture, and performances of the device in question and shall include the necessary particulars which make it possible to evaluate whether it complies with the requirements of the Directive.

(3) The particulars referred to in sub-paragraph (2) shall include the following:—

- (a) the design specifications, including the Standards which have been applied;
- (b) the necessary proof of their appropriateness, in particular where the relevant national Standards have not been applied in full, including the results of the appropriate tests carried out by the manufacturer or under his responsibility;
- (c) a statement as to whether or not the device incorporates, as an integral part, a substance referred to in paragraph 10 of Schedule 2, whose action in combination with the device may result in its bioavailability, together with data on the relevant tests conducted;
- (d) the clinical data referred to in Schedule 3;
- (e) the draft instruction leaflet.

### **Design examination certificate**

7.—(1) The notified body shall examine the application and, where the type of device complies with the relevant provisions of the Directive, shall signify approval by issuing the applicant with an EC design examination certificate.

(2) The notified body may require the application to be supplemented by further tests or proof so that compliance with the requirements of the Directive may be evaluated.

(3) The certificate shall contain the conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the type of device.

8.—(1) An applicant to whom an EC design examination certificate has been issued shall inform the relevant notified body of any modification made to the approved design.

(2) Any such modification must receive approval from the relevant notified body where it may affect conformity with the relevant essential requirements or the conditions prescribed for the use of the type of device.

(3) Any supplementary approval which is given shall be given in the form of an addendum to the EC design examination certificate.

(4) In this paragraph and paragraph 9 “relevant notified body” in relation to a design means the notified body which issued the EC design examination certificate in respect of it, except that where that body is no longer a notified body as respects tasks under this paragraph it means such other notified body as the Secretary of State shall have designated as the notified body in relation to those tasks and that design.

9. The relevant notified body—
- (a) shall withdraw any EC design examination certificate or supplementary approval given by it if it considers that the device no longer conforms with the relevant essential requirements or the conditions prescribed for the use of the type of device; and
  - (b) may withdraw the EC design examination certificate or supplementary approval if it has been given on the basis of false or misleading information.

## PART II

### SURVEILLANCE

10.—(1) The manufacturer whose quality system for manufacture and inspection is approved shall authorise the notified body to carry out the inspections, and shall supply it with all the appropriate information, which the notified body needs to ensure that the manufacturer duly fulfils his obligations arising from the approved quality system, and that information shall include—

- (a) the documentation relating to the quality system;
- (b) the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, etc.;
- (c) the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardisations, calibrations, the qualifications of the staff concerned, etc.

(2) The notified body shall periodically carry out appropriate evaluations, including inspections, in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with a report about any such evaluation.

(3) In addition, the notified body may make inspections on unannounced visits to the manufacturer, and shall supply him with a report about any such inspection.

(4) Every notified body shall communicate to the other notified bodies the information necessary to establish in respect of which quality systems it has issued, refused or withdrawn approval.

## SCHEDULE 6

Regulation 5(3)

### EC TYPE-EXAMINATION PROCEDURE (CORRESPONDING TO ANNEX 3 OF THE DIRECTIVE)

#### **Making and consideration of application**

1.—(1) An application for EC type-examination shall be made in writing by the manufacturer, or by his authorised representative, to a notified body.

- (2) The application shall include—
- (a) the name and address of the manufacturer and the name and address of the authorised representative if the application is made by the latter;

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- (b) a written declaration that an application has not been made to any other notified body;
  - (c) the documentation specified in paragraph 2 needed to allow an evaluation to be made of the conformity of a representative sample of the production in question (hereinafter referred to as “type”), with the requirements of the Directive.
- (3) The applicant shall make available to the notified body a type and such other samples as the notified body may request.

2. The documentation referred to in paragraph 1(2)(c) is that which makes it possible to understand the design, the manufacture and the performances of the device, containing in particular the following items:

- (a) a general description of the device;
  - (b) design drawings, a description of the methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of parts, sub-assemblies, circuits and other components and accessories;
  - (c) the descriptions and explanations necessary for the understanding of those drawings and diagrams and of the operation of the device;
  - (d) a list of the relevant national Standards applied in full or in part, and a description of the solutions adopted to satisfy the relevant essential requirements where the relevant national Standards have not been applied;
  - (e) the results of design calculations, investigations and technical tests carried out and other design verification data;
  - (f) a statement as to whether or not the device incorporates, as an integral part, a substance described in paragraph 10 of Schedule 2 whose action in combination with the device may result in its bioavailability, together with data on the relevant trials conducted;
  - (g) clinical data in accordance with paragraph 1 of Schedule 3;
  - (h) the draft instruction leaflet.
3. The notified body shall—
- (a) examine and evaluate the documentation;
  - (b) verify that the type has been manufactured in accordance with that documentation;
  - (c) record the items which have been designed in accordance with the applicable provisions of the relevant national Standards, and the items which have not been so designed;
  - (d) where the relevant national Standards have not been applied, carry out or have carried out the inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the relevant essential requirements;
  - (e) where the manufacturer has chosen to apply the relevant national Standards, carry out or have carried out the inspections and the tests necessary to verify whether they have actually been applied;
  - (f) seek agreement with the applicant on the place where the necessary inspections and tests will be carried out.

### **Approval**

4.—(1) Where the type complies with the provisions of the Directive, the notified body shall signify approval by issuing an EC type-examination certificate to the applicant.

(2) A certificate relating to a type shall contain the name and address of the manufacturer, the conclusions of the evaluation of the type, the conditions under which the certificate is valid and the information necessary for identification of the type.

(3) The notified body shall attach to the certificate what it considers to be the significant parts of the documentation and shall keep a copy of the certificate and of those parts of the documentation.

### **Modifications**

5.—(1) The applicant shall inform the relevant notified body of any modification made to a device in relation to which an EC type-examination certificate has been issued.

(2) Any such modification must receive approval from the relevant notified body where it may affect conformity with the relevant essential requirements or with the conditions of use specified for the device.

(3) Any such approval shall be issued, where appropriate, in the form of a supplement to the initial EC type-examination certificate.

(4) In this paragraph and paragraph 6 “relevant notified body” in relation to a device means the notified body which issued the EC type-examination certificate in respect of it, except that where that body is no longer a notified body as respects tasks under this paragraph it means such other notified body as the Secretary of State shall have designated in relation to that device or devices of that type.

6. The relevant notified body—

- (a) shall withdraw any EC type-examination certificate or supplementary approval given by it if it considers that the device no longer conforms with the relevant essential requirements or the conditions of use specified for the device; and
- (b) may withdraw the EC type-examination certificate or supplementary approval if it has been given on the basis of false or misleading information.

### **Notifications, etc.**

7. Each notified body shall communicate to the other notified bodies the information necessary to establish in respect of which devices it has issued, refused or withdrawn EC type-examination certificates and supplements.

8.—(1) A notified body shall, if so requested by another notified body, provide that other body with a copy of EC type-examination certificates, and of any supplements to them, which it has issued.

(2) A notified body shall make available to another notified body which so requests, giving reasons for its request, copies of those parts of the documentation which are attached to a certificate under paragraph 4(3), but shall not do so without having first informed the manufacturer.

## SCHEDULE 7

Regulation 5(4)

### EC VERIFICATION PROCEDURE (CORRESPONDING TO ANNEX 4 OF THE DIRECTIVE)

1. The manufacturer shall, before the start of manufacture, prepare and submit to the notified body documentation defining the manufacturing process, in particular as regards sterilisation, and all the routine, pre-established procedures to be implemented to ensure homogeneity of production and conformity of the devices with—

- (a) the type described in the EC type-examination certificate; and
- (b) the relevant requirements of the Directive.

2.—(1) The manufacturer shall undertake to the notified body to institute and keep up-dated a system of post-marketing surveillance.

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(2) The undertaking shall include an obligation for the manufacturer to notify the Secretary of State of the following events immediately on learning of them:

- (a) any deterioration in the characteristics or performances of and any inaccuracies in the instruction leaflet for, a device which might lead to or have led to the death of a patient or a deterioration in his state of health;
- (b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.—(1) The notified body shall carry out EC verification by controls and tests on the products on a statistical basis in accordance with paragraph 4.

(2) The manufacturer shall authorise the notified body to evaluate the efficiency of the measures taken pursuant to paragraph 1, by audit where appropriate.

4.—(1) The manufacturer shall present the manufactured products to the notified body in the form of homogeneous batches.

(2) A random sample shall be taken by the notified body from each batch.

(3) The devices which make up the sample shall be examined individually and appropriate tests, defined in the relevant national Standards or equivalent tests, shall be carried out to verify the conformity of the devices with the type described in the EC type-examination certificate, in order to determine whether the batch is to be accepted or rejected.

(4) Statistical control of products will be based on attributes, entailing a sampling system with the following characteristics:

- (a) a level of quality corresponding to a probability of acceptance of 95%, with a non-conformity percentage of between 0.29 and 1%;
- (b) a limit quality corresponding to a probability of acceptance of 5%, with a non-conformity percentage of between 3 and 7%.

(5) If a batch is accepted, the notified body shall draw up a written certificate of conformity, and all the devices in the batch may, subject to regulation 3(1), be placed on the market, with the exception of those devices in the sample which were found not to conform.

(6) If a batch is rejected, the notified body shall take the appropriate measures to prevent the batch from being placed on the market.

(7) If justified on practical grounds, the manufacturer may affix the EC mark during manufacture, under the responsibility of the notified body, in accordance with regulation 4(1), accompanied by the identifying logo of the notified body responsible for statistical verification.

## SCHEDULE 8

Regulation 5(5)

### EC DECLARATION OF CONFORMITY TO TYPE PROCEDURE (CORRESPONDING TO ANNEX 5 OF THE DIRECTIVE)

## PART I QUALITY SYSTEM

1.—(1) The manufacturer shall make an application in writing for evaluation of his quality system to a notified body.

- (2) The application shall be signed by or on behalf of the manufacturer and shall include—
- (a) the information and undertakings which are required by paragraph 2 of Schedule 5 to be included in an application under paragraph 1 of that Schedule, other than the information required by paragraph 2(1)(e) of that Schedule so far as it relates to research and development and design;
  - (b) the technical documentation relating to the approved type and a copy of the EC type-examination certificate.

2.—(1) Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

(2) Subject to sub-paragraph (3) below, paragraphs 3(3) and (4)(a), (b), (d) and (e), 4 and 5 of Schedule 5 shall apply for the purposes of this Schedule as they apply for the purposes of that Schedule, but as though any reference to paragraph 3(2) to (4) of that Schedule were a reference to sub-paragraph (1) of this paragraph and paragraphs 3(3) and (4)(a), (b), (d) and (e) of that Schedule.

(3) Paragraph 3(4)(b)(ii) of Schedule 5 shall not apply in respect of the desired quality of design.

## PART II

### SURVEILLANCE

3. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4. The manufacturer shall authorise the notified body to carry out all necessary inspections and shall supply it with all appropriate information, in particular:

- (a) the documentation relating to the quality system documentation;
- (b) the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardisations, calibrations, the qualifications of the staff concerned, etc.

5.—(1) The notified body shall periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

(2) In addition, the notified body may make unannounced visits to the manufacturer, and shall supply him with an inspection report.

(3) The notified body shall communicate to the other notified bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

### SCHEDULE 9

Regulation 8

#### NOTIFIED BODIES — CONDITIONS

1.—(1) The body, its director and its staff responsible for carrying out operations relating to evaluation and verification—

- (a) shall neither be, nor be the authorised representative of, the designer, manufacturer, supplier or installer of devices which they evaluate;

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- (b) shall neither be, nor represent any person who is, directly involved in the design, construction, marketing or maintenance of those devices.
- (2) Nothing in sub-paragraph (1) precludes the possibility of exchanges of technical information between a manufacturer and the body.
- 2. The body and its staff must—
  - (a) carry out operations relating to evaluation and verification with the highest degree of professional integrity and technical competence;
  - (b) be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of an evaluation, especially from those with an interest in the result of the evaluation.
- 3.—(1) The body must be able to carry out all the tasks as respects which it is or is to be designated under regulation 8, whether they are or are to be carried out by the body itself or under its responsibility.
  - (2) In particular the body must—
    - (a) have at its disposal the necessary staff; and
    - (b) possess the necessary facilities,to enable it to perform properly the technical and administrative tasks relating to evaluation and verification; and must have access to the equipment necessary for the verifications required.
- 4. The staff responsible for evaluation and verification must have:
  - (a) appropriate vocational training covering all the operations of evaluation and verification for which the body has been designated;
  - (b) satisfactory knowledge of the requirements of the controls they carry out and adequate experience of the operations of evaluation and verification for which the body has been designated;
  - (c) the ability required to draw up the certificates, records and reports to demonstrate that the controls have been carried out.
- 5. The impartiality of staff carrying out evaluations and verifications must be guaranteed, and their remuneration must not depend on the number of procedures carried out, nor on the results of the evaluations and verifications.
- 6. The body must keep itself insured against liabilities incurred in the performance of its functions, except to the extent that any liability would be met by the Crown, a government Department or a body exercising functions on behalf of the Crown.
- 7. The staff of the body must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-a-vis the competent authorities of any member State in which their activities are carried out) under the Directive or these Regulations.
- 8. The body must undertake to carry out the inspections referred to in paragraph 10(2) of Schedule 5 with a frequency to be agreed with the Secretary of State, and, once having become a notified body must fulfil the terms of that undertaking.
- 9. The body must undertake to comply with Articles 13 and 15 of the Directive (measures where EC mark has been wrongly affixed and duty of confidentiality), and, once having become a notified body, must fulfil the terms of that undertaking.



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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations (“the Regulations”) implement Council Directive [90/385/EEC](#) (“Directive”) on the approximation of the laws of the Member States relating to active implantable medical devices (OJNo. L189, 20.7.90, p. 17).

The Directive is based on the Council resolution of 7 May 1985 on a new approach to technical harmonisation and standards (OJ No. C136, 4.6.85, p. 1). It lays down essential safety requirements which active implantable medical devices (“devices”) must satisfy.

Regulation 3 provides that devices placed on the market or put into service must comply with the relevant essential requirements (set out in Schedule 2) and sets out the factors to be taken into consideration in deciding whether the device meets the essential requirements.

Regulation 4 requires devices other than custom-made devices or devices intended for clinical investigation to bear the EC mark. Regulation 4 also prohibits the use of a mark which is likely to be confused with the EC mark.

Regulation 5 provides that a device may bear the EC mark only if its manufacturer—

- (a) follows the EC declaration of conformity procedure as set out in Schedule 5 or
- (b) follows the EC type-examination procedure as set out in Schedule 6, together with
  - (i) the EC verification procedure as set out in Schedule 7, or
  - (ii) the EC declaration of conformity to type procedure as set out in Schedule 8.

Regulation 6 and Schedule 4 contain rules in respect of custom-made devices.

Regulation 7 and Schedule 4 contain rules in relation to devices intended for clinical investigation.

Regulation 8 provides for the approval of notified bodies to carry out tasks in relation to regulation 5 and Schedule 9 sets out the conditions which notified bodies must meet. Regulation 5(8) to (11) makes provision for the fees chargeable by the notified bodies for work done under the Regulations.

Regulation 9 creates offences and regulation 10 provides that the Regulations are to be regarded for the purposes of enforcement as safety regulations and safety provisions as defined in the Consumer Protection Act 1987, although they are made partly in exercise of other powers.

Transitional provisions are provided for in regulation 11.

Regulation 12 provides for the notification of decisions by the Secretary of State and the notified body.